

### International Life Sciences Institute

November 24, 1999

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Mr. Joseph Levitt Director Center for Food Safety and Applied Nutrition U.S. Food and Drug Administration 200 C Street, SW Washington, DC

RE: Docket No. 99P-2630 – CSPI Petition for Proposed Rulemaking to Establish a Daily Reference Value for "Added Sugar"

Dear Mr. Levitt:

I am aware that you are reviewing the recently submitted petition from the Center for Science in the Public Interest asking that "added sugars" be made a part of the nutrition label. The ILSI Human Nutrition Institute recently funded an analysis of carbohydrate consumption patterns using the Third National Health and Nutrition Examination Survey (NHANES III), including "added sugars". The analysis was carried out by Dr. Won Song and colleagues at Michigan State University.

Though the data are not yet published, we submitted them to the Dietary Guidelines Advisory Committee last spring. Given the new petition, we felt the same information may be of interest to you and your staff and have therefore enclosed a summary of the findings. If you would like to see any additional information, please let me know.

The Human Nutrition Institute is a division of the International Life Sciences Institute (ILSI) Research Foundation. ILSI is a nonprofit, worldwide foundation established in 1978 to advance the understanding of scientific issues relating to nutrition, food safety, toxicology, risk assessment, and the environment by bringing together scientists from academia, government, industry, and the public sector to solve problems with broad implications for the well-being of the general public. ILSI is affiliated with the World Health Organization as a nongovernmental organization and has specialized consultative status with the Food and Agriculture Organization of the United Nations.

I hope the data from our study will be useful to you. I will be pleased to answer any questions that arise about this material.

Sincerely, American Sincerely,

Suzanne S. Harris, Ph.D.

Executive Director

**Human Nutrition Institute** 

Enclosure

99P-2630

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### Relationship between Sugars Intake and Measures of Obesity and Nutrient Adequacy

### Background

In 1994, the International Life Sciences Institute's North American branch organized an expert panel to review all available literature on the role of dietary sugars and health. The proceedings of this panel's deliberation were published in the American Journal of Clinical Nutrition (62:161S-296S, 1995). One of the papers written for this panel examined intake patterns of the U.S. population using the 1987-88 Nationwide Food Consumption Survey (NFCS) and compared these data to those generated by the Food and Drug Administration in its review of sugars published in 1986 (J. Nutr. 116:S1-S216). The panel concluded that there was no evidence that sugars intake (56 grams per day or 10-12 percent of calories, based on the 1987-88 NFCS)) was related to risk of chronic disease.

The relationship between sugars intake and obesity was not evaluated with the NFCS data. Since the recent Third National Health and Nutrition Examination Survey (NHANES III) provided an opportunity to look carefully at the relationship between sugars intake and body mass index (BMI), the ILSI Human Nutrition Institute provided a grant to Dr. Won Song and Debra Keast at Michigan State University to undertake such an analysis. Dr. Harvey Anderson, who addressed the Dietary Guidelines Advisory Committee at its March meeting, served as an external advisor to the project. The analysis was designed to address the issue of nutrient adequacy as well. The data on the relationship between body mass index and sugars consumption were presented by Debra Keast at the EB'99 meeting (abstract attached).

### Methods:

The NHANES III data files include food composition values for total carbohydrate and for total sugars. The latter are defined as the sum of mono- and disaccharides (sucrose + fructose + glucose + galactose + lactose + maltose). These values came from the database of the Dietary Data Collection of the Nutrition Coordinating Center at the University of Minnesota.

To determine the value for so-called "added sugars", the foods reported in the NHANES III 24-hour recall were linked to the Food Guide Pyramid Servings database for added sugars. In this database, definition for added sugars is expanded beyond mono- and disaccharides to cover all sweeteners including:

white sugar, brown sugar, raw sugar, corn syrup, corn syrup solids, high fructose corn syrup, malt syrup, maple syrup, pancake syrup, fructose sweetener, liquid fructose, honey, molasses, anhydrous dextrose, crystal dextrose, saccharin, and aspartame that are eaten separately or used as an ingredient in processed or prepared foods.

For this definition of added sugars, teaspoons are the unit of measure, where 1 teaspoon is the quantity of a sweetener that contains the same amount of carbohydrate as 1 teaspoon of table sugar. This value was then converted to grams of added sugars (1 tsp = 4 g of added sugars) and to energy (1 tsp = 16 Kcal). The result is that the term added sugars now includes mono-, di- and oligosaccharides.

There were 733 foods, most of which were infrequently eaten and/or contained little or no added sweetener, in the NHANES III data base that did not match with a food in the Food Guide Pyramid Servings database. These foods were then hand coded to the closest available food in the Food Guide Pyramid Servings database.

Table 1 shows the means and quartile distribution for energy, fat and carbohydrate intake for some of the age/sex categories examined. In reporting data by quartiles, each of the 10 age/sex groups for which data were reported was stratified by these groups before placing the individuals into quartiles.

Statistical analysis was carried out with the SUDAAN package.

### Results

A. How do the intake patterns of adults in the NHANES III survey compare with past surveys?

Figure 1 shows the percent of energy contributed by fat and various carbohydrate components for five nationally representative surveys. The data from the 1977-78 NFCS are the data generated by the Food and Drug Administration (J. Nutr. 116:S1-S216, 1986) For this analysis, added sugar measures only mono- and disaccharides. The values for the 1988-94 NHANES and the two CSFII surveys were generated using the expanded definition of added sugars.

It is important to note that total carbohydrate intake has increased from 43 to 51 percent of calories, as encouraged by the Dietary Guidelines. An increase of total sugars accounts for less than one-half (3.5 percent) of the increase in total carbohydrate. Yet by using the USDA data base, added sugars intake appears to have increased from 12 to nearly 16 percent of calories, more than the increase in total sugars. It seems very unlikely that added sugars account for all of the increase, let alone more than the increase in total sugars.

Because there has been a fundamental change in how added sugars are calculated, it is important to examine the contribution of the definitional change to this increase. Working with Dr. Youngmee Park, who created the Food and Drug Administration database for the analysis of the 1977-78 NFCS data, and with the USDA-ARS Survey Research Branch, we have identified two possible sources of significant differences — 1) values reported for products containing corn syrups other than high fructose corn syrup; and 2) values reported for yeast bread products.

There are 648 of the 4,744 foods in the NHANES III database for which the value of added sugars (coming from the USDA database) is greater than the total sugars value (from the NCC database) lending weight to the conclusion that at least a portion of the increase seen over the 20 year span is due to the change in definition.

The Food Guide Pyramid Servings database converts all of the carbohydrate in corn syrups to sucrose equivalents, even though corn syrups can be up to 80 percent by weight oligosaccharide (degree of polymerization (DP) 3-7+). One way to estimate the impact of this difference is to assume that the average value for the non-sugar saccharides in the two most commonly used corn syrups is 70 percent. Using disappearance data from 1991, the mid-point of the NHANES III survey, these syrups represented 13.4 percent of the total dry weight of all corn-derived sweeteners and 70 percent of 13.4 percent would represent the total non-mono- and disaccharides contributed by these syrups. The average grams of added sugars calculated using the new definition of added sugars is 85.2 g/day (from 21.3 tsp). So the ball-park over estimation due to this ingredient is 8.0 g/day (0.134 x 0.7 x 85.2 g/d). This calculation, alone, would bring the estimate of added sugars intake down to 14.3 percent kcal.

The issue with yeast breads is that the Food Guide Pyramid counts all sweeteners added during the making of yeast bread. Since a portion of that sweetener is used by the yeast to make the bread rise, it is no longer present when the bread is consumed. While the change per food item is very small, the aggregate contribution may be large because of the large amount of yeast breads consumed by the population. Based on information from the baking industry, a conservative estimate of sugar consumption by the yeast and in the Maillard reaction is 75-85 percent of the sugar added to bread dough.

The mean added sugars contributed by the category yeast breads and rolls is 5.0 tsp or 20 grams per day. If 75 percent of this amount is consumed by the yeast and the Maillard reaction, then the remaining added sugars is 5 gram/day or a loss of 15 grams per day bringing the overall mean added sugars intake from 85.2 grams per day to 70.2 grams per day. This represents a reduction in the mean percent kcal from added sugars to approximately 13 percent.

By considering only these two possible explanations for the apparent increase in added sugars consumption, it appears that the best estimate of added sugars intake is approximately 13 percent of calories, a very small if any increase from the estimates made by FDA based on the 1977-78 NFCS.

### Conclusions:

Total carbohydrate and total sugars consumption has increased over the past 20 years. Total carbohydrate is now approaching the value of 55-65 percent kilocalories recommended by a number of expert groups.

- Added sugars may have increased slightly but the bulk of the increase is more likely due to a change in the definition of the term "added sugars". Certainly the increase is in proportion to the increase in total carbohydrate and total sugars consumption.
- B. Are adults with high intakes of carbohydrates, total sugars or added sugars more obese than adults with lower intakes?

These analyses were carried out only with adults (19 years of age and older) because of the uncertainty of defining obesity in children using BMI.

Figures 2 and 3 show the intake patterns for various adult age groups for fat, carbohydrate, total sugars and added sugars both in grams/day and percent kilocalories/day. Figure 4 shows the results of correlation analysis between total fat intake and various carbohydrate categories. The top half of the figure shows a positive correlation between total fat gram intake and various carbohydrate gram intakes. However, when expressed as percent of energy, there is an inverse pattern or seesaw — as percent of energy from fat goes up, the percent of energy from carbohydrate goes down and vice versa. The same pattern is apparent when the adults are arrayed by quartiles of carbohydrate intake and fat intake as percent of calories is plotted against percent calories from carbohydrate categories (Figure 5).

The average BMI for quartiles of fat intake as well as carbohydrate is shown in Figure 6. High fat (as percent kcal) consumers tend to have higher BMI than low fat consumers. The opposite is seen for carbohydrate and total sugars. For added sugars, there was no significant differences in BMI between the quartiles. Actual means are compared in Table 2.

Table 3 shows the energy, fat and sugars means for the population when arrayed by BMI category. The obese category ( $\geq$  30) reported a significantly lower total sugars and added sugars intake compared to the lean group ( $\leq$  25). This is true for all age/sex groups examined except men 19-30 years of age. For this group those classified as obese (BMI  $\geq$  30) had higher total sugars and added sugars than the other two BMI categories (Figure 7).

### Conclusions:

- Energy intake from total fat is inversely related to energy intake from carbohydrate and sugars.
- Adult BMI is inversely associated with food energy from carbohydrate, total sugars and added sugars, with the exception of men 19-30 years of age.

### C. Is a high sugars intake associated with reduced nutrient adequacy?

Figure 8 presents the percentage of the sample population falling below 2/3 of the 1989 Recommended Dietary Allowance (RDA) for the so-called "problem nutrients" by quartiles of total sugars intake (grams/day). The higher sugars intake quartiles have fewer people reporting diets with less than 2/3 the RDA. The same picture is seen with quartiles of added sugars. When the data are presented as quartiles of percent kilocalories from total sugars, individuals in the highest quartile of total sugars are more likely to fall below 2/3 of the RDA for all nutrients listed except vitamin C (Figure 9). Both vitamin A and calcium exhibit a U- shaped relationship, meaning that individuals in the lowest and highest quartiles of sugars intake had less nutrient dense diets than did those in the middle quartiles.

Table 4 shows the mean nutrient intakes by quartiles of intake as percent energy from total sugars. Table 5 shows nutrient density (mean nutrient intake/1000 kcal) arrayed by quartiles of percent kilocalories from total sugars. Here the results are mixed. For some nutrients, vitamin E and zinc, there is a downward trend as total sugars goes up perhaps due to the accompanying decline in fat intake. For vitamin C, there is a clear increase as sugars consumption increases. With the other problem nutrients, the U-shaped curve appears once again.

Figure 10 shows the nutrient density for calcium by quartiles of percent of energy from total sugars for different age groups. For all 2-18 year olds, the highest quartile has significantly lower calcium density than all other quartiles, but the lower three are not significantly different from each other. The pattern is different for adults. For example for women 19 years and older, the highest quartile of percent energy from total sugars had significantly higher calcium density than all of the other quartiles. The other three quartiles were not different from each other.

### Conclusions:

- Total and added sugars intake quartiles (g/day) are positively associated with total daily nutrient intake.
- Nutrient density of some problem nutrients is decreased in the lowest and highest quartiles of sugars.
- These relationships are different depending on the nutrient and the sex/age group examined.
- Prevalence of nutrient inadequacy was lower in the high sugars intake quartile (g/day) and higher in the high sugars energy intake quartile (percent Kcal).

Attachments: Abstract

Tables and Figures

### Abstract of EB'99 Presentation

ENERGY INTAKE FROM SUGARS AND FAT IN RELATION TO OBESITY IN U.S. ADULTS, NHANES III, 1988-94. Keast DR. Padgitt AJ. Song WO. Michigan State University, East Lansing, MI, 48824.

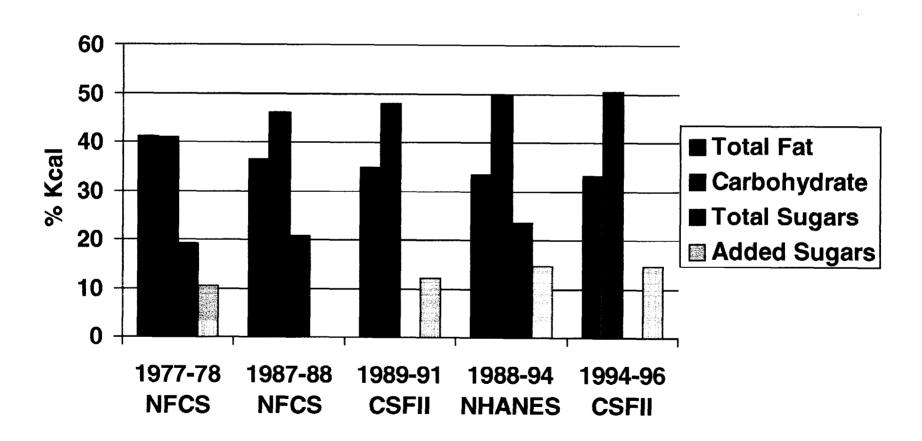
An inverse relationship between sugars and fat consumption has been implicated for obesity. Total sugars, fat and energy intakes by adults (19+y, n=15,948) in NHANES III were examined in relation to their BMI. Mean intakes of energy, fat, CHO and total sugars (sum of six added and naturally occurring sugars) were compared by age, gender and BMI subgroups, Energy intake averaged 2193±20 (SEM) Kcal/d contributed by fat (34%). CHO (50%), and total sugars (24%). The % Kcal from total sugars varied from 22% (51+y men) to 26% (19-30y women). Women age 51+y had 32% Kcal from fat and 52% Kcal from CHO; and 31-50y men had 34% Kcal from fat and 48% Kcal from CHO. 45% of U.S. adults were not obese (BMI < 25); 32% had BMI 25-29; and 22% of U.S. adults were obese (BMI  $\geq$  30). Compared to non-obese adults (BMI < 25), obese adults (BMI ≥ 30) had lower energy intake (2223±30 vs. 2077±35 Kcal/d), higher % Kcal from fat  $(33.1\pm0.3 \text{ vs. } 34.7\pm0.3\%)$ , lower % Kcal from CHO  $(50.1\pm0.3 \text{ vs. }$  $48.7\pm0.4\%$ ), and lower % Kcal from total sugars (23.8±0.3 vs. 22.9±0.3%). The trends were consistent for fat and CHO intakes in both men and women, and for total sugars intake in women. The dietary "sugars-fat seesaw" operates such that BMI is positively associated with % Kcal from fat, and inversely associated with % Kcal from total sugars. Fat intake was associated with obesity of men and women in U.S. (Supported by ILSI-RF)

Table 1. Mean and quartiles of food energy density and percent energy from macronutrients, NHANES III, 1988-19941

Food Energy and Macronutrient	Statistic ± S.E. <sup>2</sup>	All 2 + y (n=25,908)	All 6-12 y (n=3554)	Male 13-18 y (n=1097)	Female 13-18 y (n=1193)	Male 19+ y (n=7632)	Female 19+ y (n=8316)
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Food energy density	Mean	$99.7 \pm 0.4$	124.5 ± 0.9	119.9 ± 1.8	118.9 ± 1.9	95.2 ± 0.7	89.9 ± 0.6
(Kcal /	25 <sup>th</sup> %tile	$75.7 \pm 0.5$	$102.7 \pm 0.8$	$95.3 \pm 2.1$	$93.6 \pm 2.3$	$73.9 \pm 0.7$	67.1 ± 0.7
100 gram)	50° %tile	$96.2 \pm 0.5$	$120.2 \pm 0.9$	115.4 ± 2.1	113.0 ± 2.2	$92.1 \pm 0.8$	85.7 ± 0.7
	75 <sup>th</sup> %tile	119.4 ± 0.6	139.5 ± 1.2	138.3 ± 2.4	135.7 ± 2.5	112.1 ± 1.0	107.5 ± 0.9
Total Fat	Mean	33.5 ± 0.2	33.6 ± 0.2	33.5 ± 0.4	33.9 ± 0.4	33.9 ± 0.3	33.2 ± 0.2
(% Kcal)	0.58.0(1)				005.04	07.0 . 0.4	000.00
	25 <sup>th</sup> %tile	$27.6 \pm 0.2$	$28.7 \pm 0.2$	$28.3 \pm 0.7$	28.5 ± 0.4	$27.9 \pm 0.4$	26.8 ± 0.3
	50 <sup>th</sup> %tile	$33.7 \pm 0.2$	$33.6 \pm 0.2$	$33.3 \pm 0.5$	33.6 ± 0.5	$34.2 \pm 0.3$	$33.4 \pm 0.2$
	75 <b>°</b> %tile	39.5 ± 0.2	38.6 ± 0.3	38.8 ± 0.5	38.8 ± 0.6	39.9 ± 0.3	39.9 ± 0.2
Total Carbohydrate	Mean	50.8 ± 0.2	53.7 ± 0.3	52.5 ± 0.5	54.0 ± 0.7	48.4 ± 0.4	51.0 ± 0.3
(% Kcal)	25° %tile	$43.3 \pm 0.3$	$47.7 \pm 0.4$	$46.0 \pm 0.6$	$47.2 \pm 0.6$	$40.9 \pm 0.4$	43.1 ± 0.4
(70 1100.)	50 <sup>th</sup> %tile	50.8 ± 0.2	53.3 ± 0.3	52.6 ± 0.5	$53.7 \pm 0.7$	$48.1 \pm 0.4$	50.6 ± 0.3
	75 <sup>th</sup> %tile	58.0 ± 0.3	59.6 ± 0.4	58.3 ± 0.6	61.5 ± 0.7	$55.7 \pm 0.4$	58.3 ± 0.3
Total	Mean	24.9 ± 0.2	28.1 ± 0.3	28.5 ± 0.5	29.9 ± 0.8	22.8 ± 0.4	24.1 ± 0.2
Sugars	_						
(% Kcal) <sup>3</sup>	25" %tile	17.1 ± 0.2	$21.3 \pm 0.4$	$21.2 \pm 0.5$	$20.9 \pm 0.7$	$15.1 \pm 0.3$	$16.2 \pm 0.2$
	<b>50'<sup>in</sup> %tile</b>	$23.9 \pm 0.2$	$27.1 \pm 0.4$	$27.7 \pm 0.6$	$28.3 \pm 0.8$	$21.7 \pm 0.3$	$23.0 \pm 0.2$
	75 <sup>th</sup> %tile	$31.3 \pm 0.3$	$33.7 \pm 0.4$	34.4 ± 0.6	36.9 ± 0.7	28.9 ± 0.4	30.3 ± 0.3
Added	Mean	15.7 ± 0.2	18.1 ± 0.3	20.3 ± 0.5	21.4 ± 0.8	14.7 ± 0.3	14.7 ± 0.2
Sugars							
(% K̃cal)⁴	25" %tile	$7.9 \pm 0.1$	$11.4 \pm 0.3$	$12.9 \pm 0.6$	$12.2 \pm 0.7$	$7.2 \pm 0.3$	$6.9 \pm 0.1$
	50 <sup>th</sup> %tile	$14.1 \pm 0.2$	$17.0 \pm 0.4$	$19.1 \pm 0.6$	$19.6 \pm 0.8$	13.1 ± 0.3	12.8 ± 0.2
	75° %tile	$21.4 \pm 0.3$	$23.5 \pm 0.5$	$26.0 \pm 0.6$	$28.6 \pm 0.9$	$20.1 \pm 0.4$	$20.3 \pm 0.4$

- <sup>1</sup> Sample age 2 years or more includes those with reliable and complete dietary interview, and excludes pregnant and/or lactating women.
- <sup>2</sup> Statistics are sample-weighted and standard errors are calculated by linearization variance estimation method of SUDAAN.
- \* Total sugars (g/day) is the sum of sucrose, galactose, maltose, glucose, fructose, and lactose intakes.
- \* Percentage of energy from teaspoons (1 tsp = 16 Kcal) of added sugars, where 1 teaspoon is the quantity of a sweetener that contains the same amount of carbohydrate as 1 teaspoon of table sugar.

Figure 1. Trends in Macronutrient Intake: U.S. Adults





# Figure 2. Total Fat, Carbohydrate, and Sugars Intake by Gender and Age

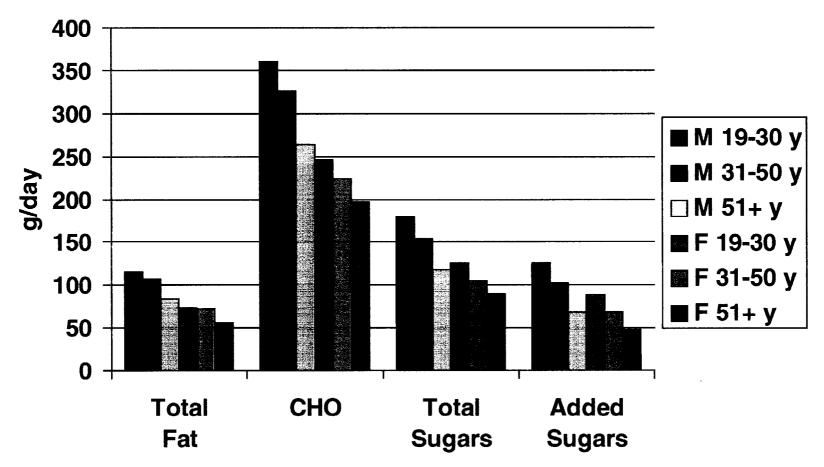
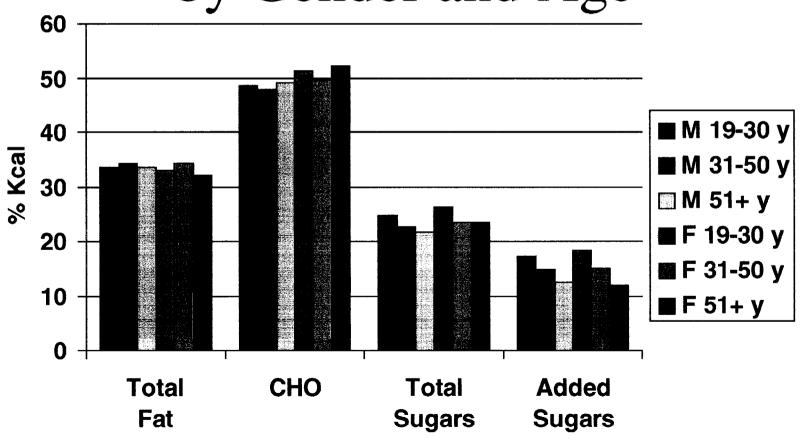


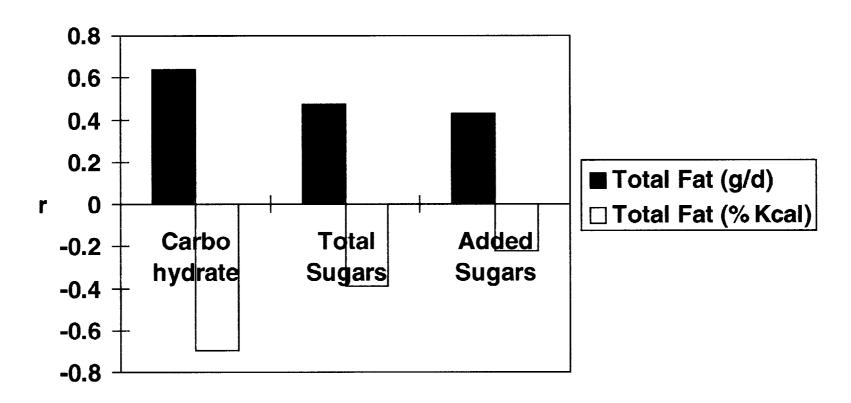


Figure 3. Percent Energy from Total Fat, Carbohydrate, and Sugars by Gender and Age



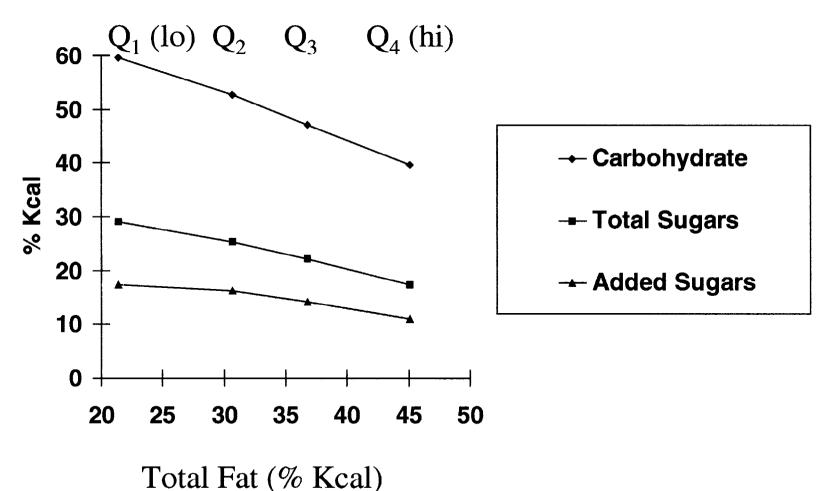


## Figure 4. Correlations of Total Fat Versus Carbohydrate and Sugars



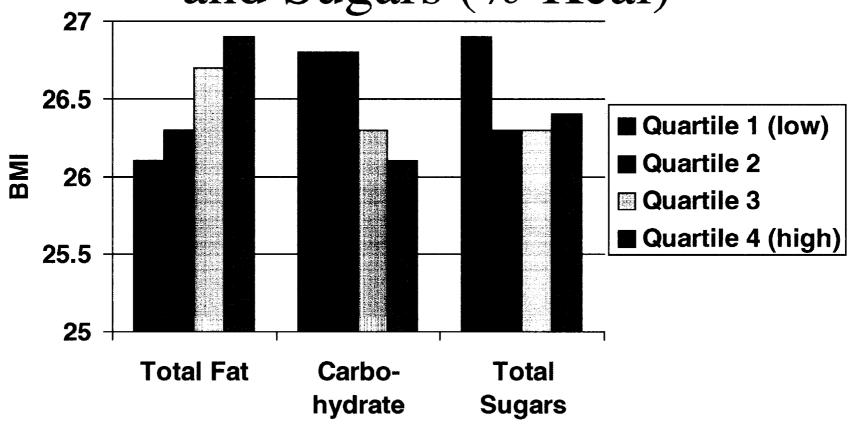


## Figure 5. Carbohydrate and Sugars Intake by Quartiles of Total Fat (% Kcal)





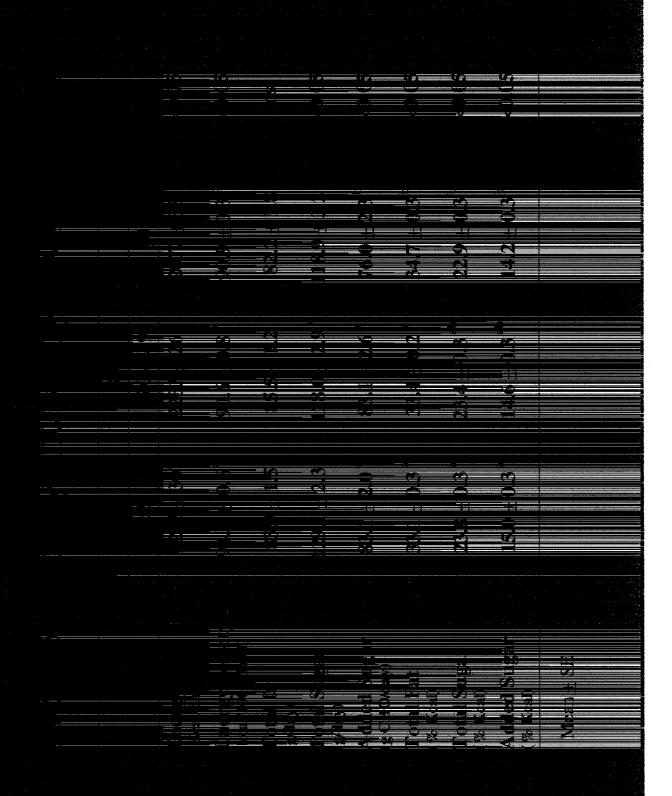
# Figure 6. Body Mass Index by Quartiles of Total Fat, Carbohydrate, and Sugars (% Kcal)



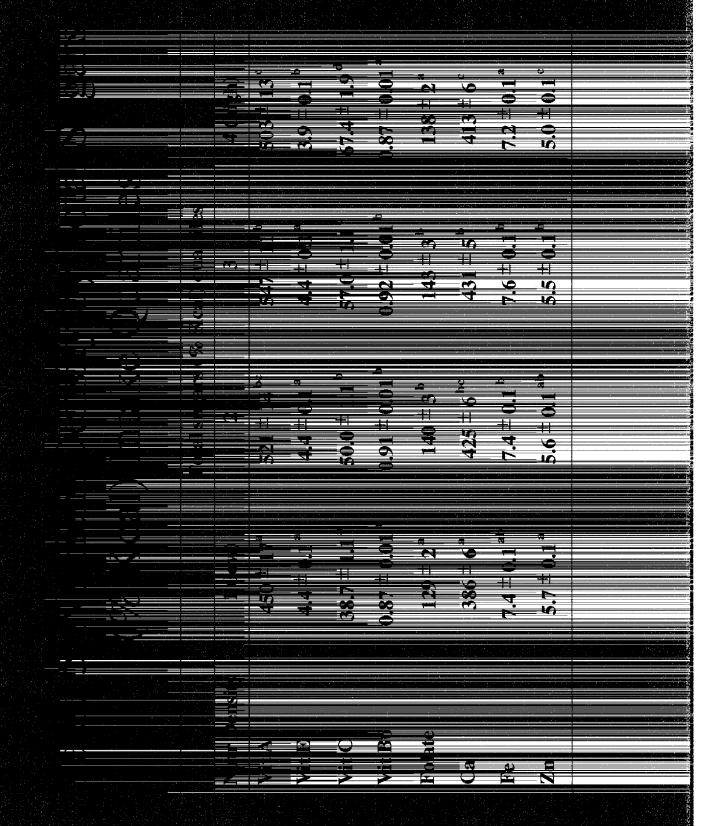




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			3240 ± 0.24 3240 ± 0.24 3240 ± 0.24	
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				<b>)</b>



### Figure 7. Total and Added Sugars Intake of Non-obese and Obese Men 19-30 y

